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(54) Circular keratotomy with insert
for myopia correction

(57) A space maintainer (e.g. ring)
(50) is provided for use in a circular
keratotomy surgical procedure. Space
maintainer (50) is inserted in an

incision (30) cut into the cornea (20)
of an eye (22) of a patient. The
incision (30) circumscribes the optical
zone (32) of the eye (22) to cause the
cornea (20) to flatten (34). Space
maintainer (50) maintains the cornea
(20) in the flattened position (34).

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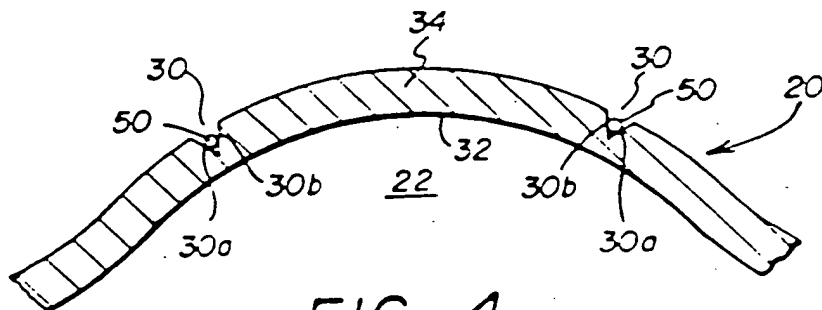
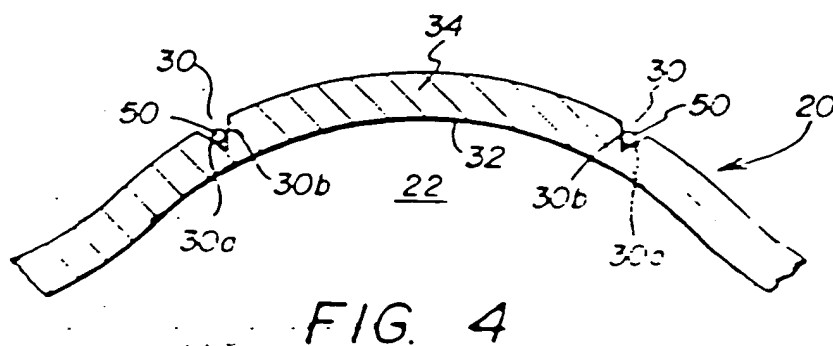
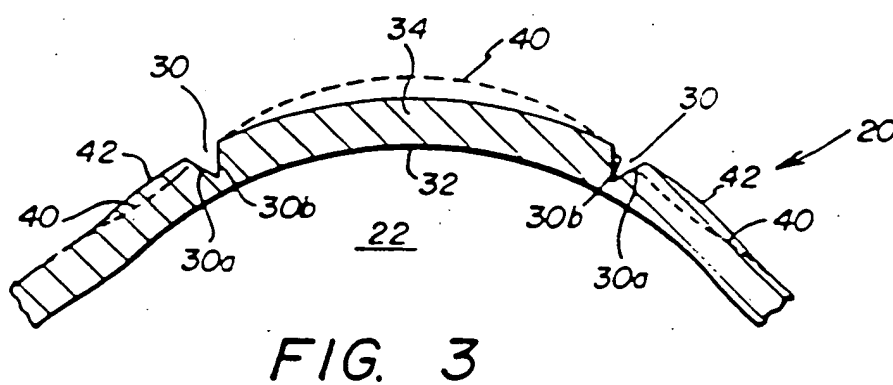
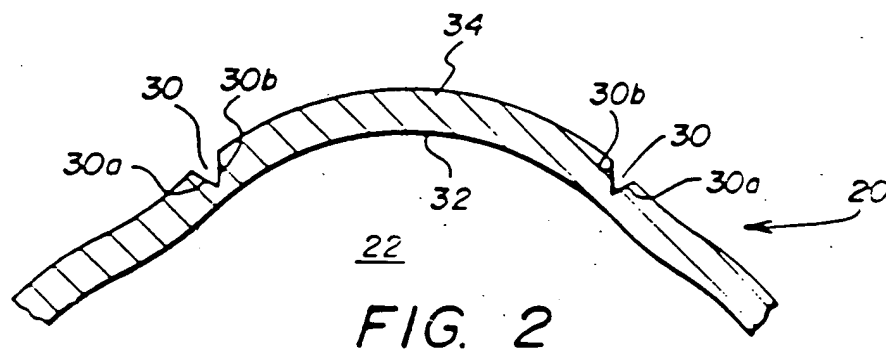
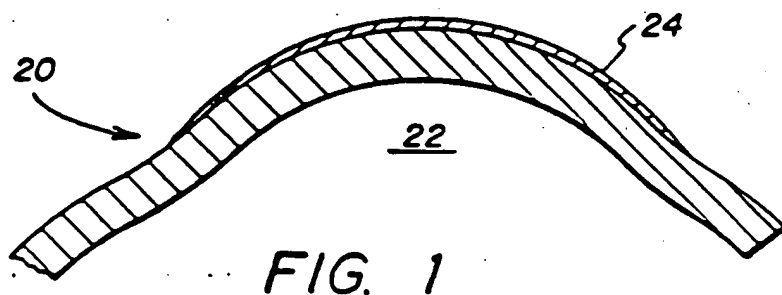


FIG. 4

0 8 9 9 3 6 9 6

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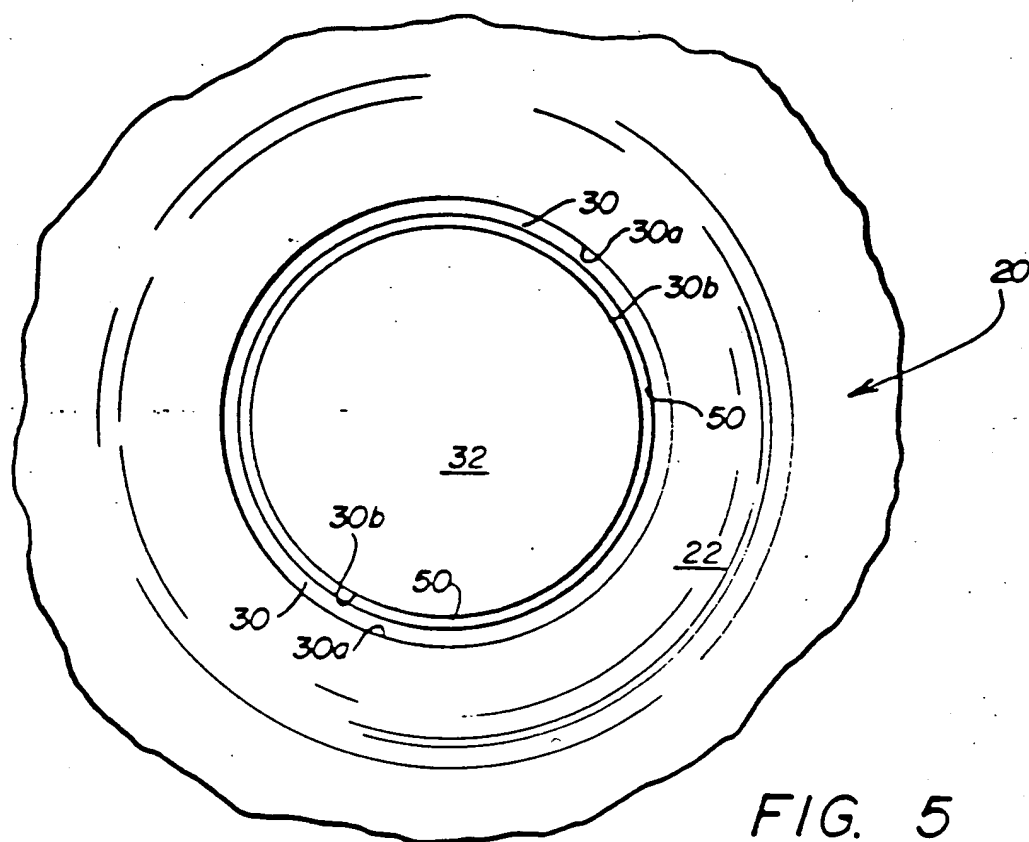


FIG. 5

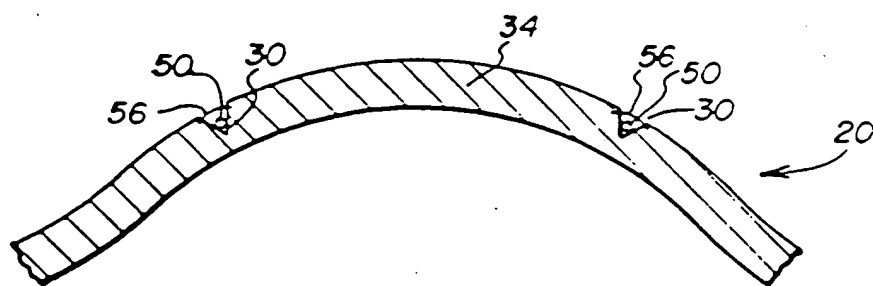


FIG. 6

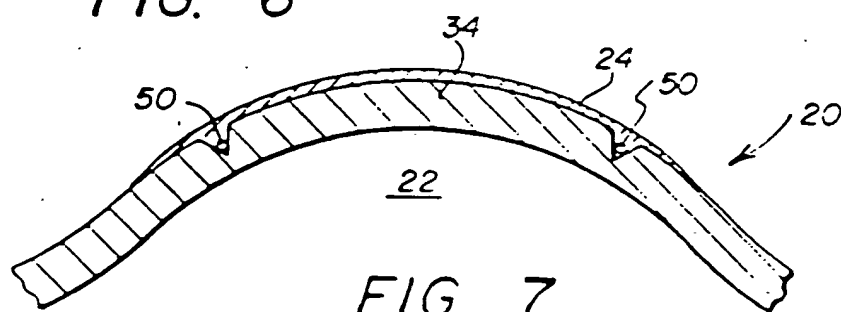
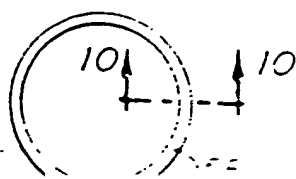
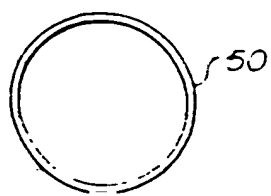


FIG. 7



SPECIFICATION**Circular keratotomy with insert for myopia correction****Technical Field**

- 5 This invention relates to corrective eye surgery, and more particularly to circular keratotomy and an insert for myopia correction.

Background Art

- The process by which one visually perceives involves light entering the eye in parallel rays, which are generally bent as they pass through the cornea and lens of the eye. In the normal eye, the light rays converge, or focus, on the retina at the back of the eyeball. Electrical impulses then transmit a sharp image to the brain.

- A common vision problem involving an improperly shaped eyeball is nearsightedness (myopia). In the nearsighted vision problem, the eyeball is usually too long or the cornea too curved, so that the light rays entering the eye come to a focal point in front of the retina. Eyeglasses and contact lenses change the focal point of the light entering the eye to provide corrected vision for nearsighted vision problems.
- Another approach to correct nearsightedness is to change the curvature of the cornea so that images fall directly on the retina. A corneal operation termed radial keratotomy has been used by Dr. Svyatoslav Fyodorov of Moscow, Russia. In Dr. Fyodorov's procedure fourteen to sixteen radial cornea incisions are made of varying length and depth into the cornea of an eye. The incisions extend from the outer edge of the cornea towards the center of the cornea. These incisions induce peripheral cornea staphyloma resulting in central corneal flattening. This flattening causes the curvature of the cornea to be reduced which in turn compensates for axial myopia.

- Although radial keratotomy comprises a relatively simple surgical operation and has been shown to provide an average correction of about 1.9 diopters, it has been found that such correction is temporary. It has been found that in many cases, the cornea returns to its original curvature and the original error in vision returns. It has also been found that the radial incisions are difficult to control in length and depth since the incision is through almost nine-tenths of the cornea's thickness. These incisions introduce a risk of perforation of the cornea during surgery. Furthermore, it has been found that the radial incisions cause the patient to experience glare sensitivity for night vision since the radial incisions are made close to the optical zone of the eye.

- A need has thus developed for improved keratotomy procedures for the correction of myopia vision problems in which improved long-term vision correction is achieved. Furthermore, a need has arisen for improved keratotomy procedures in which the corneal incisions are controlled to minimize the risk of perforation of the cornea. A need has further arisen for a keratotomy procedure in which corneal incisions are

- positioned away from the optical zone of the eye to reduce patient glare sensitivity.

Disclosure of the Invention

- In accordance with the present invention, a circular keratotomy procedure is provided together with an insert for substantially eliminating the problems heretofore associated with radial keratotomy.

- In accordance with the present invention, a space maintainer for use in corneal keratotomy wherein an incision is made into the cornea of a patient, the incision circumscribing the optical zone of the eye to cause the cornea to flatten is provided. The space maintainer includes a ring for insertion into the circular incision for maintaining the cornea in the flattened position.

- In accordance with another aspect of the present invention, a method for the surgical correction of myopia is provided. The method includes the step of cutting an incision into the cornea of a patient wherein the incision circumscribes the optical zone to cause the cornea to flatten. A spacer is inserted into the incision for maintaining the cornea in the flattened position.

Brief Description of the Drawings

- For a more complete understanding of the present invention and for further advantages thereof, reference is now made to the following Detailed Description taken in conjunction with the accompanying Drawings, in which:

- FIGURE 1 is a cross-sectional view of a cornea;
- FIGURE 2 is a cross-sectional view of the cornea of FIGURE 1 with the epithelial layer removed and a circular incision made according to the present invention;

- FIGURE 3 is a cross-sectional view of the cornea of FIGURE 2 wherein central cornea flattening is illustrated;

- FIGURE 4 is a cross-sectional view of the cornea of FIGURE 3 illustrating the insert of the present invention disposed within the circular incision;

- FIGURE 5 is a top plan view of the cornea illustrated in FIGURE 4;

- FIGURE 6 is a cross-sectional view of the cornea of FIGURE 4 illustrating the incision having been sutured;

- FIGURE 7 is a cross-sectional view of the cornea of FIGURE 6 and a newly grown epithelial layer;

- FIGURE 8 is a top plan view of an embodiment of the present insert;

- FIGURE 9 is a top plan view of an alternate embodiment of the insert of the present invention and

- FIGURE 10 is a cross-sectional view taken generally along section line 10-10 of the insert illustrated in FIGURE 9.

Detailed Description

- FIGURE 1 is a cross-sectional view of a cornea 10. The cornea 10 is shown in cross-section along a vertical plane. The cornea 10 is composed of an outer epithelial layer 12 and an inner stromal layer 14. The epithelial layer 12 is shown as a thin, curved layer on the outer surface of the cornea 10. The stromal layer 14 is shown as a thicker, curved layer beneath the epithelial layer 12. The cornea 10 is shown in a cross-section that is slightly curved, representing its natural shape. The optical zone of the cornea 10 is indicated by a dashed line 16, which is a circular area centered on the optical axis of the eye. The optical axis is shown as a vertical line passing through the center of the cornea 10. The optical zone 16 is the area of the cornea 10 through which light rays pass to enter the eye. The optical zone 16 is shown as a circular area with a dashed boundary line 16. The optical zone 16 is the area of the cornea 10 through which light rays pass to enter the eye. The optical zone 16 is shown as a circular area with a dashed boundary line 16.

to the present invention. Cornea 20 includes epithelial layer 24.

FIGURE 2 illustrates eye 22 with epithelial layer 24 removed. A circular groove 30 is cut in cornea 20 to a depth of approximately 0.2 to 0.7 millimeters. Circular groove 30 circumscribes the optical zone, generally identified by the numeral 32 of eye 22 and has a diameter of approximately eight millimeters. It therefore can be seen that circular groove 30 is disposed away from optical zone 32 to eliminate glare sensitivity heretofore associated with radial keratotomy procedures. Circular groove 30 has a width of approximately 0.2 millimeters and is defined by sidewalls 30a and 30b. Circular groove 30 can be formed using a corneal trephine in which the depth of cut can be precisely controlled.

FIGURE 3 illustrates the results of the incision of circular groove 30 within cornea 20. The incision of circular groove 30 in cornea 20 induces peripheral cornea staphyloma resulting in central corneal flattening in the area of optical zone 32. The curvature of cornea 20 in the area of optical zone 32 is reduced to thereby compensate for axial myopia. In comparing FIGURES 2 and 3, it can be seen that central corneal area 34 of cornea 20 has flattened from the position illustrated in FIGURE 2. This initial position is illustrated in FIGURE 3 via the dotted line 40. It can also be seen in FIGURE 3 that peripheral portions 42 of cornea 20 have protruded above their initial position, being higher than line 40. The flattening of central corneal area 34 results in the shortening of eye 22 to correct for myopia and in a flatter and therefore optically weaker cornea.

Referring simultaneously to FIGURES 4 and 5, the insert of the present invention is illustrated, and is generally identified by the numeral 50. Insert 50 is disposed within circular groove 30 for maintaining sidewalls 30a and 30b of circular groove 30 apart during healing of the incision which forms circular groove 30. Insert 50 forces and maintains sidewalls 30a and 30b apart until sufficient scarring tissue closes circular groove 30 to thereby maintain central corneal area 34 of cornea 20 in the flattened position shown in FIGURE 3. Insert 50 may comprise, for example nylon, extruded PMMA, polypropylene or similar materials.

FIGURE 6 illustrates the use of sutures 56 for temporarily maintaining insert 50 in place within circular groove 30 during healing of the incision forming circular groove 30.

FIGURE 7 illustrates insert 50 permanently in place by normal scarring which has taken place between sidewalls 30a and 30b of circular groove 30. FIGURE 7 further illustrates a newly grown epithelial layer 24.

FIGURE 8 illustrates insert 50 in greater detail. Insert 50 comprises a circular ring having a

diameter of approximately eight millimeters.

Circular ring 50 has a circular cross-sectional area having a diameter of approximately 0.1 to 0.5 millimeters.

FIGURE 9 illustrates an insert 58 for insertion into circular groove 30 (FIGURE 4) having a configuration similar to insert 50. Insert 58 has a triangular cross-sectional area as illustrated in FIGURE 10 for more closely matching sidewalls 30a and 30b of circular groove 30 when inserted. The length of a side of insert 58 is approximately 0.3 millimeters.

It therefore can be seen that the present circular keratotomy for myopia correction provides for a circular incision circumscribing the optical zone of an eye. The circular incision is disposed away from the optical zone to avoid glare sensitivity heretofore present with radial keratotomy surgical procedures. The depth of the circular incision and the diameter of the incision control the amount of central cornea flattening and the resulting correction. The present invention further provides for an insert for maintaining the cornea in a flattened position to prevent the cornea from returning to its original error. The insert maintains the incision open thereby permitting corneal flattening until normal scarring takes place.

Whereas the present invention has been described with respect to specific embodiments thereof, it will be understood that various changes and modifications will be suggested to one skilled in the art and it is intended to encompass such changes and modifications as fall within the scope of the appended claims.

CLAIMS.

1. A space maintainer for use in corneal keratotomy wherein an incision is made into the cornea of a patient, the incision circumscribing the optical zone of the eye to cause the cornea to flatten comprising:

means for insertion into the circular incision for maintaining the cornea in the flattened position.

2. The space maintainer of Claim 1 wherein said means for insertion comprises ring means.

3. The space maintainer of Claim 2 wherein said ring means has a circular cross-sectional area.

4. The space maintainer of Claim 2 wherein said ring means has a triangular cross-sectional area.

5. A method for surgical correction of myopia comprising the steps of:

cutting an incision into the cornea of a patient circumscribing the optical zone thereby causing the cornea to flatten, and

inserting a spacer into the incision for maintaining the cornea in the flattened position.

6. A space maintainer for use in corneal

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keratotomy substantially as herein described with
reference to and as illustrated by the
accompanying drawings.

7. A method for surgical correction of myopia
5 substantially as herein described with reference to
and as illustrated by the accompanying drawings.

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